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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,376	09/29/2000	Anand R. Baichwal	540.1040	1823

7590

07/03/2002

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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/676,376

Applicant(s)

BAICHWAL ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of request for extension of time (granted and amendment both filed 4-11-02 and information disclosure statement filed 6-11-02 is acknowledged. Claim 14 has been canceled and claims 1, 15-16, 21, 24, 42, 43, 45, 46, and 61 have been amended as requested.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention
2. Claims 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Recitation of "first portion" and "second portion" is indefinite since these are relative terms and no standard for measuring the degree intended appears to be provided.
4. Recitation of "extragranularly" is indefinite. Examples 11 and 12 of the instant specification recite extragranular medicament, however this is granulated. Therefore, the scope intended to be encompassed is unclear.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims <sup>1-13, 15-17,</sup> 1-17, 21-25, 32-44, 61-67, 69-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (5,399,359; hereafter '359) in view of Baichwal et al (WO 97/26865; hereafter '865).

'359 teaches oxybutynin xanthan gum/locust bean gum sustained release compositions comprising a pH modifying agent such as sodium carbonate or sodium bicarbonate. The compositions provide sustained release at least about 24 hours and are in ratios within the instant ranges. Manipulation of the amounts of ingredients such as the pH modifying agent would have been obvious to one skilled in the art at the time of the invention to increase or decrease the degree of cross-linking of the polysaccharides. See Abstract; C 3, L 24- C 5, L 13; Examples; Claims. '359 does not teach the limitation where the pH modifying agent is an organic acid.

'865 is relied upon for teaching equivalence of organic acids with the cationic cross-linking agents of '359. '865 does not explicitly teach combining two strength enhancing agents, however it would have been obvious to one skilled in the art at the time of the invention to do so to provide an additive effect of enhanced strength.

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does  
("mixtures  
thereof")

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '359 and '865 to achieve an additive effect of enhanced strength.

### **Response to Arguments**

7. Applicant's arguments filed 4-11-02 have been fully considered but they are not persuasive. Applicant argues that there is no suggestion to incorporate an organic acid

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in '359 to facilitate the release of a medicament from a dosage form. '359 teaches that the sustained release matrix includes a cationic cross-linking agent capable of cross-linking with the gelling agent. This agent increases the gel strength of the formulation when it is exposed to an environmental fluid, preventing an initial burst of drug release from the formulation. Therefore, it is submitted that inclusion of the organic acid taught equivalent to the cross-linking agents by '865 would facilitate the release of the medicament from the dosage form since it facilitates the sustained release of the formulation. Applicant's arguments stating that the pH modifying organic acid is not incorporated into the sustained release granulate but instead is added after the sustained release excipient has been prepared is not found persuasive. Claims 1-64 are composition claims and are not product-by-process claims. Regarding the process claims 65-67 and 69-72, whether the organic acid is added to the heteropolysaccharide/homopolysaccharide gum blend or with a medicament does not appear to be critical. Either way results in a mixture of the heteropolysaccharide/homopolysaccharide gum, medicament, and organic acid. The critical crosslinking taught by '359 occurs upon exposure to gastric fluid after administration and after production of the formulation.

8. Claims <sup>1-13, 15-72</sup> 1-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal et al (5,399,359; hereafter '359) in combination with Baichwal et al (WO 97/26865; hereafter '865) and further in combination with Baichwal et al (5,478,574; hereafter '574).

'359 and '865 are relied upon for all that they teach as previously stated.

'574 teaches inclusion of a surfactant in xanthan gum/locust bean gum compositions provides a bimodal or multi-phase controlled release of a therapeutically active ingredient. '574 also teaches that such xanthan gum/locust bean gum compositions are effective for delivering active agents such as diltiazem.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '359 and '574 to achieve a bimodal or multi-phase controlled release of a therapeutically active ingredient in a strong formulation.

### ***Response to Arguments***

9. Applicant's arguments filed 4-11-02 have been fully considered but they are not persuasive. Applicant argues that there is no suggestion to use organic acids as pH modifying agents as currently claimed and that '574 does not cure the deficiencies of '359 and '865. Previous comments (paragraph 7 of the instant Office Action) regarding the issue of whether '359 and '865 are deficient are again applicable. '359 teaches that the sustained release matrix includes a cationic cross-linking agent capable of cross-linking with the gelling agent to increase the gel strength of the formulation when it is exposed to an environmental fluid. Therefore, it is submitted that inclusion of the organic acid taught equivalent to the cross-linking agents by '865 would facilitate the release of the medicament from the dosage form since it facilitates the sustained release of the formulation. Applicant's arguments stating that the pH modifying organic acid is not incorporated into the sustained release granulate but instead is added after the sustained release excipient has been prepared is not found persuasive. Claims 1-

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64 are composition claims and are not product-by-process claims. Regarding the process claims 65-67 and 69-72, whether the organic acid is added to the heteropolysaccharide/homopolysaccharide gum blend or with a medicament does not appear to be critical. Either way results in a mixture of the heteropolysaccharide/homopolysaccharide gum, medicament, and organic acid. The critical crosslinking taught by '359 occurs upon exposure to gastric fluid after administration and after production of the formulation.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
June 28, 2002

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600